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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,427

10/28/2003

Kurt-Reiner Geiss

7390-X03-020

4477

27317 7590 09/03/2008  
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Applicants' Response filed May 27, 2007 is acknowledged. The subject matter under consideration are those methods of treating extreme physical stress in a human comprising administering at least 50 mg of L-theanine, claims 19, 22 and 23. Claims 20, 21 and 24-32 remain withdrawn from consideration by the Examiner, as drawn to non-elected inventions, 37 CFR 1.142(b).

Information Disclosure Statements filed May 27, 2008 and June 2, 2008 are further acknowledged and have been reviewed. Each document requires a publication date.

Co-pending application US 2004/0120985 is noted.

In the last Office Action claims 19, 22 and 23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. It was asserted the recitations in claim 19 "including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous system" and "including neurotransmitters, dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected" render the claims indefinite. It is unclear whether or not claim limitations are intended. It was asserted the recitation "extreme physical stress" is indefinite. The metes and bounds of "extreme" cannot be precisely determined. It was asserted the recitation "peripheral controls" is indefinite. Although it appears Applicants intend to include serum prolactin levels and neurotransmitters among peripheral controls, the metes and bounds of "peripheral controls" cannot be precisely determined.

The Examiner regrets the inadvertent typing error of the term “system” in place of the recited term “controls” in claim 19.

Applicants argue “these phrases are clear from reading the claim.” Applicants refer to passages in the specification and dictionary definitions.

A review of the passages in the specification and definitions fails to provide a persuasive argument. With respect to the recitations beginning with the term “including,” it remains unclear whether or not claim limitations are intended. The claim language, “including,” is analogous to the terms “such as” or “for example.” The term “extreme physical stress” is relative. Parameters set forth in a stress test are not herein claimed.

While the distinctions between central and peripheral nervous systems are clear, the organism as a whole acts to maintain homeostasis, maintenance of internal equilibrium by adjusting its physiological processes. The metes and bounds of “peripheral controls” cannot be precisely determined.

The rejection of record of claims 19, 22 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention, is maintained.

Claims 19, 22 and 23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the last Office Action. The claims contains subject matter that was not described in the specification – based on Applicants’ specific citations in the specification - in such a way as to reasonably convey

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to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It was asserted the recitation “as evidenced by raised serum prolactin levels” lacks support in the specification as filed because in paragraph [0025] of the specification, measurement of the hypophyseen hormone prolactin is discussed, but no “raised serum prolactin level” is recited. Applicants now cite paragraph [0039]. Accordingly, the rejection of record directed to this specific matter is withdrawn.

It was asserted the recitation “resting the human” lacks support in the specification as filed because in paragraph [0027] of the specification, a recovery phase is noted, but no “resting” is recited. Applicants now cite paragraph [0042]. Accordingly, the rejection of record directed to this specific matter is withdrawn.

It was asserted the recitation “the peripheral controls” lacks support in the specification as filed because in paragraph [0035] of the specification, peripheral hormonal control and regulating system are discussed, but the recitation “peripheral controls” is claimed and is broader. Applicants now cite paragraph [0051]. The recitation in paragraph [0051] states it may be assumed that the mechanisms lay in the central neurotransmitter system and at the switch points between central electrical brain activity and the peripheral hormonal control and regulating system. Accordingly, the rejection of record directed to this specific matter is withdrawn

It was asserted the recitation “...neurotransmitters dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected,...” lacks support in the specification as filed because in paragraph [0025] of the specification, the recited

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hormones are discussed, but their being “substantially unaffected” is absent. Applicants now cite paragraph [0046]. Accordingly, the rejection of record directed to this specific matter is withdrawn.

The rejection of record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the last Office Action directed to new matter, is withdrawn.

Claims 19, 22 and 23 were also rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

It was asserted claim 19 recites “treating extreme physical stress” and “to complete regeneration.” There is insufficient written description for these claim limitations in the disclosure because according to Stedman’s Medical Dictionary, “stress” is *inter alia* any physical or psychological stimulus that can produce mental tension or physiological reactions that may lead to illness. Further, according to Stedman’s Medical Dictionary, “regeneration” is any regrowth of lost or destroyed parts or organs.

Applicants argue the pending claims must be given their broadest reasonable interpretation.

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Applicants' argument is persuasive with respect to the recitation "treating extreme physical stress." However, the recitation "to **complete** regeneration" is not adequately described within its broadest reasonable interpretation. The term has been applied outside its generally recognized definition that would reasonably be accepted by one skilled in the medical community.

The rejection of record of claims 19, 22 and 23 under 35 U.S.C. 112, first paragraph, is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juneja et al., Trends of Food Science & Technology.

Juneja teaches the oral administration of L-theanine, an amino acid in green tea that promotes relaxation, promotes the generation of  $\alpha$ -brain waves and lowers blood pressure without inducing drowsiness. The dosage range is 50-200 mg. As disclosed on page 200 under Lowering blood pressure, L-theanine was administered to spontaneously hypertensive rats (SHR). Such rats would have reasonably been considered extremely physically stressed. Juneja teaches the regulation of blood pressure is highly dependent on catecholaminergic and serotonergic neurons in both

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the brain and the peripheral nervous systems. Strenuous exercise raises prolactin levels. In the SHR, blood pressure was already elevated prior to the administration of L-theanine. Blood pressure was measured before and after administration. See Figure 4 on page 202. Theanine lowered blood pressure through its peripheral nervous system effects on blood vessels. Administration of theanine resulted in the generation of alpha waves in the occipital and parietal regions of the brain, which are known to indicate an awake, alert and relaxed physical and mental condition. Juneja discusses the effect of theanine on neurotransmitters in the right column on page 203. Direct administration of theanine into brain striatum caused a significant increase in dopamine release in a dose-dependent manner.

Juneja further discloses an enzymatic method to manufacture theanine on an industrial scale. See the top left column on page 204.

In view of Juneja's teaching, it would have been reasonable to expect the administration of L-theanine after stressing would result in the same relaxation effect. Such would have been obvious in the absence of evidence to the contrary because L-theanine was administered to spontaneously hypertensive rats (SHR) wherein blood pressure was already elevated prior to the administration of L-theanine. A clear relaxation effect was noted.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone



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number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 1, 2008

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614